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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/505,304

07/11/2005

Ian Revie

1781-0010

6005

28078 7590 04/22/2008

MAGINOT, MOORE & BECK, LLP

CHASE TOWER

111 MONUMENT CIRCLE

SUITE 3250

INDIANAPOLIS, IN 46204

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

04/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Notice of Amendment

In response to the arguments filed on January 9, 2008, amended claim 22, canceled claim 21 and new claims 25-27 are acknowledged. The current rejections of the claims *stand*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2-6, 8, 12-15, 19-20, 22-23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al. (U.S. Patent No. 6,478,802) in view of Gillies et al. (U.S. Patent No. 6,272,370).

In regard to claims 2-6, 8, 12-15, 19-20, 22-23, Kienzle, III et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the instrument bearing a plurality of markers rings arranged in a predetermined pattern, which are more reflective than the surface of the instrument (see Figs. 1-2 and Col. 4, Lines 25-43), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the reel drill bit relative to the

receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. teach that it is well known within the art of localizing devices to use an optical localizer that employs a stereoscopic camera system to view infrared light emitters or reflectors that are placed on the surgical instruments and that any arrangement of emitters that allows the localizer to determine the pose of the drill emitter coordinate frame with sufficient accuracy may be used without departing from the instant invention. However, Kienzle, III et al. are silent with respect to a plurality of markers rings are arranged in a predetermined pattern on the surface of the shaft. Gillies et al. teach of an analogous endoscopic apparatus comprised of an elongate shaft with a plurality of MR-visible markers 6 disposed at the distal end to provide easily identifiable reference points for trackability and localization under MR imaging and X-ray fluoroscopy (see Figure 1 and col. 25, lines 39-43). The markers 6 can be formed of radioopaque materials, such as gold, platinum or tantalum, which are more reflective than the copolymer of the shaft 2 of the microcatheter 1 (see col. 25, lines 10-53). As seen in figures 2 and 4a-b, Gillies et al. teach of placing the radioopaque materials in rings around the shaft of the instrument and wherein the planes defined by the axially spaced edges of each marker 6 are parallel to one another and perpendicular to the axis of the shaft 2. **In regard to claims 25-27**, Gillies et al. teach of placing the MR-visible markers along its length, having marker placed at a proximal portion of the shaft (see Col. 13, Lines 23-30). It would have been obvious to one skilled in the art at the time the invention was made to place a plurality of marker rings around the shaft of the drill bit in the apparatus of

Kienzle, III et al. in order to more accurately define the location and orientation of the shaft as it enters the body as taught by Gillies et al.

Claims 7, 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al. (U.S. Patent No. 6,478,802) in view of Gillies et al. (U.S. Patent No. 6,272,370) in further view of Ben-Haim (U.S. Patent No. 6,203,493).

In regard to claims 7, 16 and 24, Kienzle, III et al. and Gillies et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the shaft bearing a plurality of markers rings arranged in a predetermined pattern (see Figs. 1-2 and Col. 4, Lines 25-30), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the reel drill bit relative to the receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. are silent with respect wherein the rings are marked on a sleeve which is fitted onto the instrument. Ben-Haim teaches a similar tracking device for an endoscope comprised of a sheath 20 having a plurality of sensors 22 spaced along the axis of the endoscope (see Figure 1). It would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the instrument of Kienzle, III et al. and Gillies et al. with a sheath containing the markers 6, in the manner disclosed by Ben-Haim, as Ben-Haim demonstrates that sheaths containing radio-opaque markers for placement over an surgical device are well known in the art.

Response to Arguments

Applicant's arguments filed January 9, 2008 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, It would have been obvious to one skilled in the art at the time the invention was made to place a plurality of marker rings around the shaft of the drill bit in the apparatus of Kienzle, III et al. in order to more accurately define the location and orientation of the shaft as it enters the body as taught by Gillies et al.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., permanent marker rings) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also states that it would not have been obvious to one skilled in the art to place a plurality of markers around the shaft of the drill bit in the apparatus of Kienzle

based on the teaching of Gillies as the marker would likely wear off. Examiner disagrees. Applicant states that there are no “wearing issues” with respect to the use of Gillies’ cerebral catheters. However, it is well known in the art that the gold, platinum or tantalum MR-visible markers 6 should be fixedly secured to the shaft so as not to become dislodged within the patient during use. Furthermore, Gillies inherently discloses that the markers may be placed along the entire length of the shaft as the MR visibility is variably adjustable based on requirements related to degree of signal loss for device localization and positioning, enhancement along the shaft of the device, enhancement around the body of the device, visibility of the proximal and distal ends of the device, degree of increased background noise associated with the device movement, and other factors which either increase or suppress background noise associated with the device (see Col. 23, Lines 37-45).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739

4/15/08

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